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Pharmaceutical Advertising 2022

Vietnam: Law & Practice

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VIETNAM

Law and Practice

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1. PHARMACEUTICAL ADVERTISING: REGULATORY FRAMEWORK

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

The advertising of medicines in Vietnam is mainly governed by the following regulations:

- the Law on Advertising No 16/2012/QH13;
- the Law on Pharmacy No 105/2016/QH13; and
- Decree No 54/2017/ND-CP (as amended).

In addition, regulations on drug advertising are also mentioned in two professional pharmaceutical trade association guidelines:

- the Code of Ethical Practices issued by Pharma Group under the European Chamber of Commerce in Vietnam ("PG Code"); and
- the Voluntary Codes on Business Ethics in the Vietnam Pharmaceutical & Biopharmaceutical Sector, issued by the Vietnam Pharmaceutical Companies Association ("VNPCA Code").

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The PG Code applies to all Pharma Group members and all of their employees (whether on indefinite term, definite term, or seasonal labour contracts) as well as third-party agencies representing the interests of Pharma Group member companies. The VNPCA Code applies to all VNPCA members and related organisations and individuals.

Neither of these codes has legal value.

2. SCOPE OF ADVERTISING AND GENERAL PRINCIPLES

2.1 Definition of Advertising

"Advertising" is defined as the implementation of various means to present to the public products, goods and services for profit; products and services not for profit; and organisations and individuals which are trading and providing the presented products, goods and services, except for news, social policies and personal information.

There is no specific definition of drug advertising under current regulations in Vietnam – only the general definition of advertising.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

"Drug information", under regulations in the law on the collection and provision of such information, means information about a drug, including indications, contraindications, dosage, administration, adverse effects, and information relevant to the quality, safety and efficacy of the drug provided by responsible facilities on behalf of pharmaceutical authorities, healthcare professionals and those using the medication.

The current regulations are silent on the provision of drug information to authorities and those using the medication; only regulations on the provision of drug information to medical and healthcare professionals are available. Specifically, drug information can be provided to healthcare professionals through one of three forms:

- drug introducers (medical representatives);
- drug information documents; and
- drug introduction seminars.

The biggest difference between drug information provision and drug advertising is the main targeted subjects – healthcare professionals for drug information and users/consumers of the medication for drug advertising. In addition, drug advertising is only allowed for drugs satisfying all of the following conditions, ie, they must:

- be non-prescription;
- not be subject to limited use or subject to use under the supervision of a physician; and
- have valid marketing authorisation (MA).

Under the Law on Advertising, print products and events are means of advertising; and any materials (such as patient leaflets) or programmes aiming to provide patients with information about drugs are subject to regulations on drug advertising.

2.3 Restrictions on Press Releases regarding Medicines

There are no specific regulations on press releases for medicinal products in Vietnam.

2.4 Comparative Advertising for Medicines

Under the Law on Advertising, it is prohibited to use advertising that directly compares the prices, quality or efficiency of the advertiser's products with those of other products of the same kind (including medication).

3. ADVERTISING OF UNAUTHORISED MEDICINES OR UNAUTHORISED INDICATIONS

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

It is only permissible to provide drug information for drugs that have been granted MA or import licences. For drugs with import licences, the only form of drug introduction allowed is seminars. Thus, it is not possible to provide information on unauthorised medication.

In addition, the grounds to create drug information to be provided to healthcare professionals include only:

- the Vietnamese National Drug Formulary;
- the medicine package insert approved by the Ministry of Health (MOH); and
- professional documents/instructions relating to the medicine, either issued or accepted by the MOH.

Thus, it can be interpreted that it is not permitted to provide information about indications that have not yet been approved by the authority.

Pre-information Procedure

Before releasing drug information documents or conducting drug introduction seminars, it is necessary to obtain a certificate of drug information content (approval) from the Drug Administration of Vietnam (DAV) for drug information documents, or from the provincial Department of Health for drug introduction seminars.

It is not required to obtain approval from the authorities before conducting drug information provision via drug introducers (medical representatives), provided they have been granted

specific medical representative cards for such activity.

3.2 Provision of Information during a Scientific Conference

As mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, it is not possible to provide information on unauthorised medication or indications, regardless of the form of information provision.

Pre-information procedure

Before conducting a scientific conference directed at healthcare professionals, it is necessary to obtain a certificate of drug information content from the provincial Department of Health.

In addition, at least three working days before holding the conference, the establishment that has been granted the certificate of drug information content must send the provincial Department of Health written notification of the time and place of the conference, accompanied by a copy of the granted certification of drug information content.

Furthermore, if there is a change to the time or place mentioned in the certificate of drug information content, the establishment must notify the local Department of Health where the conference is being organised at least one working day before the conference date.

3.3 Provision of Information to Healthcare Professionals

Companies are not allowed to provide healthcare professionals with information about medicines/indications that have not yet been approved by the authority. Thus, it is not possible for companies to send information on unauthorised medicines or unauthorised indications to healthcare professionals.

Information on unapproved indications (off-label use) of an active ingredient, or unapproved active pharmaceutical ingredients may be discussed in a non-promotional scientific exchange, if approved by the Vietnamese authorities in charge.

3.4 Provision of Information to Healthcare Institutions

Information on unauthorised medicines or unauthorised indications may be sent to healthcare institutions in the context of clinical trials. Such communications will not be considered as drug advertising or promotion; rather, the communication would be stipulated in the clinical trial agreements or related documents.

3.5 Publication of Compassionate Use Programmes

The regulations are silent on the publication of compassionate use programmes. In practice, such programmes may be published. For example, the MOH announced a programme on early access to unapproved Molnupiravir for the treatment of COVID-19.

4. ADVERTISING PHARMACEUTICALS TO THE GENERAL PUBLIC

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is strictly prohibited to advertise prescription medicines. Advertising is allowed only for over-the-counter (OTC) medication which is not subject to restrictions on use and does not need to be given under the supervision of a physician as recommended by a relevant state agency, and which has valid MA licences in Vietnam.

An approval (in the form of a certificate) on drug advertising content must be obtained from the DAV before conducting the advertising activity

relating to the advertising content. The advertising activity must comply with the approval.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Requirements for Drug Advertising Content

Drug advertising content must include the following:

- name of the medicine;
- active ingredients or herbs;
- administration;
- dosage;
- contraindications, recommendations for particular sectors of the population (pregnant or breastfeeding women, etc);
- cautions and warnings;
- undesirable effects;
- name and address of manufacturer;
- the sentence "*Đọc kỹ hướng dẫn sử dụng trước khi dùng*" ("Read instructions carefully before use");
- at the bottom of the first page of drug advertising content, the serial number of the certificate of drug advertising content of the MOH and the date of issue must be clearly stated;
- for multi-page advertising content, the pages must be numbered and the number of pages and the page on which readers can obtain details on the product must be stated on the first page; and
- a note on supporting documents specifying the information cited in the documents (the citation must ensure accurate communication of information, without presenting the information in a way that causes misunderstanding about the safety and efficacy of the medicine).

If the advertisement has audio, it must be presented with the following content:

- name of the medicine;
- active ingredients or herbs;
- administration;
- contraindications, recommendations for particular sectors of the population (pregnant or breastfeeding women, etc);
- name and address of manufacturer; and
- the sentence "*Đọc kỹ hướng dẫn sử dụng trước khi dùng*" ("Read instructions carefully before use").

Prohibited Content

The information and images below may *not* be used in drug advertising content.

- Information and images specified in the Law on Advertising, such as unfair competition; the words "best", "the best", "only", "number one" or words with similar meaning without legitimate documents proving such, as prescribed by the Ministry of Culture, Sports and Tourism (such as the results of a market survey or certificate obtained from a competition, etc); and another person's image, words or text without obtaining that person's consent.
- Misleading contents about the ingredients, effects, indications or origin of the drug.
- Content creating the following understanding: this drug is number one; this drug is better than all others; using this medicine is the best measure; use this medicine without consulting a doctor; this drug is completely harmless; this drug has no contraindications; this drug has no undesirable effects; this drug has no harmful effects.
- Sentences, words and images that are overly deductive, leading to misunderstandings as to the effects, indications and effectiveness of the drug, or exaggerating the effects, indications and effectiveness of the approved drugs.
- The effect of each ingredient of the drug to advertise the effects of the drug itself, or con-

fusing the effect of each ingredient with the effect of the finished drug.
- Words and phrases, such as: "root treatment", "elimination", "special treatment", "top", "top of list", "first-time", "selection", "high quality", "100% guarantee", "safety", "stop", "immediate reduction", "quit immediately", "completely cured", "assured", "don't worry", "recommended", "hotline", "consultation phone", and words and phrases with similar meanings.
- Indications for treatment of tuberculosis and leprosy, sexually transmitted diseases, insomnia, cancers and tumours, diabetes or other similar metabolic disorders, viral hepatitis and emerging dangerous diseases; indications for sexual arousal; and indications for drug addiction cessation treatment.
- Clinical research results, non-clinical research results, testing results, or bioequivalence results which have not yet been approved by the MOH to advertise as drug information.
- The name, position, prestige, testimonials, or thank-you letters of organisations and individuals to advertise the drugs.
- The origin of drugs or medicinal ingredients to advertise the drugs.
- Pictures, names and symbols of medical staff.
- Images of animals and plants on the list of endangered, precious and rare species prioritised for protection.
- Sentences and words of advice to recommend a medicine.
- Images of patients to describe the medical condition or use of the drug, which are inconsistent with the drug-related documents and professional guidelines issued or recognised by the MOH.

In addition, advertising content is required to conform with: (i) the Vietnamese National Drug Formulary; (ii) the medicine package insert and labels approved by the MOH; and (iii) professional documents/instructions relating to the medicine issued or accepted by the MOH. This means, in principle, that it is not permitted to include information in the advertising content that is not included in these documents.

Drug Prices

The main policy for medicinal product pricing in Vietnam is that drug manufacturers, exporters, importers, MA holders and wholesalers/distributors are free to set the prices of their products, and compete on prices, but are still liable to the law. Pharmaceutical establishments must declare their drug prices to the DAV but no approval for the declared price is issued by the authority.

None of the documents (i), (ii) or (iii) mentioned above include the drug price. Thus, the drug price should not be mentioned in the advertising.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Under Vietnamese Law

It is prohibited for medical representatives of companies selling medication to approach patients, to collect information regarding the medical records or medical prescriptions of patients; or to discuss or require information related to patients.

Under the PG Code

"PG members must not answer requests from individual members of the public for advice on personal medical matters. Enquirers must be referred to their personal physicians. This includes toll-free information services. Medical representatives must never discuss medical matters with patients in any forum, including health fairs, pharmacies, hospitals, and physicians' waiting rooms, even if approached directly by a patient, nor may they instruct patients on how to use company products. Patients must be advised to seek advice directly from their phy-

sician, who, in turn, may contact PG members for further information. Disease awareness campaigns or patient education program[me]s can be supported by PG members by providing a grant to a competent medical association which is authorised to conduct such campaigns.

PG members may support the work of independent patient associations but must ensure that their involvement has been declared and is transparent, that all of the arrangements comply with this Code and applicable Laws, and that a written agreement is in place. PG members must not influence the operation of the funded patient associations. The independence of this association must be fully kept."

Under the VNPCA Code

No specific provision is mentioned. In interactions with all relevant parties, a member company is committed to:

- implementing the highest ethical standards;
- implementing fully and responsibly all laws and regulations in force;
- encouraging medical professionals, government officials, and others working with the company, to always respect and apply the appropriate ethical standards that conform to the VNPCA Code; and
- ensuring that the company interacts in a professional manner and aims to bring benefits to the patients, as per the VNPCA Code.

5. ADVERTISING TO HEALTHCARE PROFESSIONALS

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Drug information provided to healthcare professionals must include the following: the name of the medicine, its composition, concentration, strength, dosage form, indications, contraindications, dosage and administration, the use of the medicine in specific sectors of the population, information related to warnings and safety, and other necessary information.

Similar to drug advertising to the general public, the grounds to create drug information for provision to healthcare professionals include: (i) the Vietnamese National Drug Formulary; (ii) the medicine package insert approved by the MOH; and (iii) professional documents/instructions relating to the medicine issued or accepted by the MOH. Thus, in principle, information that is not included in the documents above may not be provided. Accordingly, the drug price should not be mentioned in drug information content provided to healthcare professionals.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

As mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, drug information provided to healthcare professionals must be included in specific documents, including the approved package insert. The Summary of Product Characteristics ("SmPC") is only required for new drugs under regulations in Vietnam while the package insert will be required for any drugs (new and generic) registered in Vietnam. The content of the package insert is similar to that of the SmPC.

If a piece of information is not mentioned in the documents above, the pharmaceutical entity first needs to register such information with the DAV by submitting a variation dossier (Variation 39: Adding and/or updating information to provide product information and advertising) to obtain the DAV's approval for the use of the document/information for provision of drug information.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

See **5.2 Reference to Data Not Included in the Summary of Product Characteristics**. Any information not included in the three documents mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals** needs to be approved first by the DAV in terms of a variation registration dossier before it can be used in product information and advertising.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Medical representatives who are in charge of directly providing drug information to healthcare professionals of pharmaceutical establishments are prohibited from providing drug information that is not as accurate as the information submitted to or verified by the regulatory authority, and from publishing drug information or documents that are not verified by the regulatory authority.

Thus, companies are not allowed to provide reprints of journal articles to healthcare professionals referring to medical and scientific information on unapproved new uses for approved drugs.

5.5 Medical Science Liaisons

There is no specific definition or requirement for medical science liaisons (MSLs) in Vietnam. However, as with medical representatives, it is presumably not permitted to proactively discuss information on unauthorised medicines or indications with healthcare professionals at an MSL.

6. VETTING REQUIREMENTS AND INTERNAL VERIFICATION COMPLIANCE

6.1 Requirements for Prior Notification/ Authorisation

Approval must be obtained from the DAV for various aspects of a drug advertisement, such as the content, layout and form, and the applicant must comply with the approval in the course of advertising. The advertising of drugs before obtaining the DAV approval is prohibited.

6.2 Compliance with Rules on Medicinal Advertising

There are no specific regulations on what arrangements companies must have in place to ensure compliance with the rules on medicinal advertising. There are only requirements for medical representatives who are in charge of directly providing drug information to healthcare professionals. In particular, medical representatives must meet the following requirements:

- they must have a college degree or higher in medicine or pharmacy; and
- they must be hired and trained by pharmaceutical businesses in professional skills and operations related to drug introduction and legal documents on pharmacy.

Medical representatives must be granted a “medical representative card” by the pharmaceutical business.

7. ADVERTISING OF MEDICINAL PRODUCTS ON THE INTERNET

7.1 Regulation of Advertising of Medicinal Products on the Internet

Advertising of medicinal products on websites follows general regulations on drug advertising specified in **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

If the advertising content has multiple pages or is a sound or video recording with multiple scenes, the pages or scenes of the advertisement must appear consecutively, pausing long enough for viewers to read all the information; plus pages and scenes with product information must be stationary and not moving so that viewers have time to take in the product information. The advertising script included in the application for content approval must describe how the content pages will appear for multi-page advertisements.

The advertising of medicines in this form must be separate and multiple medicines must not be advertised at the same time, to avoid misunderstanding.

7.2 Advertising of Medicines on Social Media

Advertising medicines on social media is not prohibited, provided that the relevant advertising content has been previously approved by the DAV.

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

In principle, drug information documents can only be provided to the correct (approved) subjects. This means that if information is approved to be provided to healthcare professionals, websites containing the information must include access restriction so that only healthcare professionals can access them.

7.4 Provision of Disease Awareness Information to Patients Online

Pharmaceutical businesses may not provide disease awareness information and/or materials to patients online. Companies can only support disease awareness campaigns or patient education programmes by providing support to a competent medical association which is authorised to conduct such campaigns.

7.5 Online Scientific Meetings

Regulations on online scientific meetings are similar to those for offline meetings in Vietnam.

Pharmaceutical companies are allowed to sponsor scientific meetings or congresses and/or virtual attendance by healthcare professionals at these events; no special restriction is stipulated under Vietnamese law. However, the sponsorship should be in compliance with corresponding guidelines from relevant pharmaceutical associations, if any.

Under Decision No 06/2020/QD-TTg of the prime minister dated 21 February 2021 on the organisation and management of international conferences and seminars in Vietnam, an "international conference or seminar" is defined to cover any conference or seminar involving foreign elements which is organised in the form of a face-to-face meeting in Vietnamese territory or in the form of an online meeting with at least one location for streaming in Vietnamese territory, including:

- conferences and seminars organised by Vietnamese organisations with foreign participation or sponsorship; and
- conferences and seminars organised by foreign organisations.

"Vietnamese organisations" are those established under Vietnamese law and managed by a Vietnamese authority, such as central state or local administrative agencies. "Foreign organisations" include those permitted by an authority to operate in Vietnamese territory.

Online conferences may be considered "international" events if they meet the definition above.

Before being held, online international meetings must be registered with the authority in Vietnam. This also means that the content of such meetings will be evaluated by the authority, based on Vietnamese law.

There are no specific rules on accessing conference recordings, materials, etc, after the date of the conference. In practice, attendees can typically access such recordings or materials after the conference.

8. PHARMACEUTICAL ADVERTISING: INDUCEMENT/ANTI-BRIBERY

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The key legislation governing anti-bribery and anti-corruption matters in Vietnam is the Anti-corruption Law and Penal Code. Under this law, corruption-related offences, including the giving and promising of bribes, the receiving of bribes, the "brokerage" of bribes, and embezzlement are strictly prohibited and the violators may be subject to criminal liability. Given the broad definitions under the Anti-corruption Law, any persons who have certain positions and authority in both the public and private sectors can be deemed "office holders" liable for offences relating to bribery.

For the act of giving/promising bribes, the law does not distinguish between bribes given to an individual office holder or to an organisation. In theory, giving or promising bribes to healthcare organisations or healthcare professionals, especially those who concurrently hold managerial titles in a healthcare organisation, is strictly prohibited and may be subject to criminal liability.

In practice, corruption or bribery charges are applied to individuals rather than organisations. Depending on the value of the benefits given and the severity of the crime, the penalty for an individual will be a monetary fine ranging from VND20 million to VND200 million (about USD880 to USD8,800) or six months' to 20 years' imprisonment.

8.2 Legislative or Self-Regulatory Provisions

It is prohibited for medical representatives to use material benefits to influence healthcare professionals or those using the medication to make them write more prescriptions or purchase more of the medication.

9. GIFTS, HOSPITALITY, CONGRESSES AND RELATED PAYMENTS

9.1 Gifts to Healthcare Professionals

Vietnamese Law

It is not specified by Vietnamese law under what circumstances pharmaceutical companies may offer gifts to healthcare professionals (HCPs).

PG Code

"Gifts (examples include but are not limited to sporting or entertainment tickets, sight-seeing travels including sight-seeing travels in con-

junction with events, electronic items, social courtesy gifts, wreaths, etc) provided to healthcare professionals ("HCPs") (either directly or indirectly) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited.

Items of medical utility

- Items of medical utility may be offered or provided by PG member companies to HCPs if such items are of modest value (no independent value and not for personal benefit), do not offset routine business practices, are directly beneficial to enhancing the provision of medical services and patient care, and in line with Vietnamese laws.
- Items of medical utility should be given to HCPs on an occasional basis only, even if each individual item is appropriate.
- Items of medical utility can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient, and in line with Vietnamese laws.

Educational items that enhance Patient Care

- Informational and educational items that enhance Patient Care provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.
- These informational and educational items can include the company name but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The total value for items of medical utility, informational and educational items that enhance Patient Care given to HCPs must be less than VND2,000,000 per HCP per year (cumulative).

Items of medical utility, informational and educational items that enhance Patient Care must never be given to HCPs or medical institutions, organisations or associations for the personal benefit of the HCP or to influence the recommendation, prescription, purchase or usage of medicines and must never be formative of a quid pro quo arrangement."

VNPCA Code

"Companies should not pay/give cash or gifts to healthcare professionals.

The company may offer gifts that are items that have educational, medical or patient benefit (eg, medical books) to health workers. These gifts must conform to the specialised field of health workers."

The VNPCA Code does not provide a specific threshold limit for such gifts.

9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is considered as a type of product promotion. Under the applicable law on product promotion, promoted or promotional products may not include medicines for human use, including those permitted for circulation as regulated by the Ministry of Health (except where the sales promotion is dedicated to traders involved in selling medication). As such, providing medical samples as a product promotion activity to HCPs is prohibited in Vietnam.

The same prohibition is also regulated under the PG Code and VNPCA Code. However, these codes additionally provide three exemptions: (i) samples for tenders as requested by the hospitals; (ii) samples of vaccines and biological products for quality-testing purposes by a relevant authority before circulation in the market; and (iii) samples requested by the health authorities.

9.3 Sponsorship of Scientific Meetings

Vietnamese Laws

It is not specified under Vietnamese law whether pharmaceutical companies may sponsor scientific meetings or congresses and/or attendance by HCPs at these events:

PG Code

"Sponsorship to individual HCPs to attend events:

- PG members can organise or sponsor HCPs (either directly to HCPs or through their organisation) to attend in-country events or international events, provided that such international events derive participants from many countries. Any sponsorship for HCPs to attend such events must not be conditional upon an obligation to promote, recommend, prescribe or purchase, supply or administer any pharmaceutical product. Such sponsorship must:
  (a) Always be in line with the primary purpose of enhancement of scientific and medical knowledge, through obtaining information that is critical to the improvement of patient care and overall enhancement of healthcare delivery, and such sponsorship must be supported by written documentation;
  (b) Avoid any conflict of interest as stipulated in relevant Vietnamese laws and conform to the internal regulations of the HCP's organisation; and
  (c) Comply with the PG Code and applicable laws.
- A PG member's sponsorship for HCPs to attend events must be subject to the following conditions:
  (a) The sponsorship must have a legitimate scientific and medical knowledge enhancement purpose, and strictly follow applicable Vietnamese laws;
  (b) PG member must inform the HCP's organisation and ensure full transparency about invitations or sponsorship for HCPs to attend events, including details of the sponsorship and the agenda of the event; and
  (c) The event program[me] must not include standalone entertainment, sight-seeing or side trips, or other inappropriate activities or be located at an inappropriate venue.
- A PG member's sponsorship for HCPs to attend events must comply with the following requirements:
  (a) The selection of HCPs must be based on the expected added value of the event for their area of expertise, following a fair selection process and not give any potential appearance of inappropriateness or bias, and avoid any issue of conflict of interest. The PG member must ensure that the HCPs have obtained official permission from their organisation to attend the event;
  (b) Transportation and accommodation should be provided as per reasonable standards considering the nature and venue of the event and the level of involvement of the HCPs. For example, business class tickets for local travel, luxurious or extravagant accommodation must not be provided. Sponsorship to standalone entertainment, sight-seeing or side trips, or other leisure or social activities is not allowed. There must be a reasonable and justified timeframe for the departure and return of the HCPs to and from the event location;
  (c) Hospitality provided to the HCPs must be limited to refreshments and/or meals incidental to the main purpose of the event and its value must be moderate and reasonable as judged by local standards. Alcoholic drinks are not allowed during the event lunch. Refreshment during dinner can have alcoholic drinks, within a

reasonable limit. Applicable laws must be respected;

(d) Companies must not pay any costs associated with individuals accompanying the HCP, except in cases of medical necessity. HCPs can have accompanying individuals with them at their own expense, but PG members will not involve [themselves] in logistical arrangements for accompanying people. Accompanying people (except in cases of medical necessity) should not be allowed to attend any event for HCPs;

(e) All sponsorship arrangements must be appropriately documented before and after the event.

Specifically regarding sponsorship for HCPs to attend international events, there must be commitment from HCPs who attend the event to share the benefit of knowledge gained on their return to Vietnam, such as through presentation to other HCPs (no honorarium shall be provided) or a report to their organisation or other academic/medical institution".

Events organised in foreign countries

"PG members must not organise or sponsor HCPs to attend events that take place outside of their home country unless it is appropriate and justified to do so from a logistical or security point of view. PG members can organise or sponsor HCPs to attend international events, as these derive participants from many countries. In this case, the host country regulations and standards can be applied, unless otherwise provided by Vietnamese laws."

VNPCA Code

"Any financing of companies offered to individual healthcare professionals may not be tied to conditions and/or obligations and/or suggestions to prescribe, recommend use, or promote any medicines."

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

Vietnamese Laws

It is not specified under Vietnamese law whether pharmaceutical companies may organise or sponsor cultural, sports or other non-scientific events at scientific conferences.

PG Code

"PG members must not organise or sponsor recreational events such as tours, sports, leisure activities, year-end parties for medical institutions, anniversary events of medical institutions, etc. PG members are prohibited from offering any kind of compensation to HCPs for participation in the events."

VNPCA Code

It is not specified under the VNPCA Code whether pharmaceutical companies may organise or sponsor cultural, sports or other non-scientific events at scientific conferences.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Vietnamese Law

It is not specified under Vietnamese law whether pharmaceutical companies may provide grants or donations to HCPs or healthcare institutions.

PG Code

- "No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, supports, consulting contracts or education or practice-related items) may be provided or offered to an HCP that inappropriately influences prescribing, recommending, purchasing, supplying or administering medicines or a commitment to continue to do so (ie, no quid pro quo).
- Donations are prohibited to be given directly to individuals.
- Donations must be in written agreement with examination and treatment establishments,

and public hospitals. It must be clearly stipulated that the donation recipients have to: (i) follow the procedures for the preparation, evaluation and approval of the foreign non-governmental aid amount in compliance with applicable regulations; and must (ii) manage and use the donation only for humanitarian objectives in accordance with its commitments in the agreement and not use the donation for any other purposes."

VNPCA Code

"Funding, scholarships, subsidies, support, consulting contracts, education, etc, should not be provided to healthcare professionals to exchange, set the conditions of recommended use or drug prescription, or influence the ethics and independence of the related healthcare professionals. Companies should only sponsor, grant scholarships, subsidise, etc, with the purpose of supporting legal education, scientific research and/or medical research."

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Providing rebates or discounts on drugs to HCPs is considered a type of product promotion and is prohibited under Vietnamese law.

The law is silent on providing healthcare institutions with discounts. However, the procurement of any products and services by a public healthcare institution must comply with the Law on Tender, where the tender price must be approved by the relevant authority. Normally, the price listed in such tender contract is the listed price without discount.

9.7 Payment for Services Provided by Healthcare Professionals

Vietnamese Laws

It is not specified under Vietnamese law whether it is possible to pay for services provided by HCPs.

PG Code

"HCPs may be engaged as consultants and advisors for services such as: speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, translating medical documents, interpretation at medical meetings, writing a medical article and/or giving medical training, and participating in market research, where such participation/services, involves honorariums.

The arrangements covering legitimate provisions of such services must meet the following conditions:

(i) The engagement does not interfere with the interest of the HCP's employer and the employer has no objection against the engagement;
(ii) A written contract with the engaged HCP is put in place which specifies the nature of the services to be provided and the basis for payment of those services;
(iii) Payment to HCP service providers must be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed and must be adequately documented. Payments of service fees must not be made in advance. Cash payment is prohibited;
(iv) Only engage HCP service providers where there is a legitimate need for their services clearly identified and documented in advance, and: the criteria for selecting consultants must be directly related to the identified need; the consultants must have the expertise nec-

essary to provide the service; the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need; the compensation for the services must be reasonable and reflect the fair market value.

The amount of the honorarium for local speakers/moderators at local meetings should be at fair market value. The honorarium for foreign speakers at local meetings or local speakers at international meetings should be at the level of normal practice in the speaker's home country."

VNPCA Code

"A healthcare professional who renders counselling services or is a rapporteur should be paid a reasonable remuneration and travel expenses, accommodation and meals to provide services as per market cost."

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

No prior authorisations or notifications (eg, employer consent, regulatory authority approval) are required in relation to any of the activities described in this section.

10. PHARMACEUTICAL COMPANIES: TRANSPARENCY

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

Under Vietnamese law, every individual and organisation in the private sector has the right to report acts of corruption and bribery where they are aware of such misconduct.

In terms of transfers of value not subject to anti-corruption and anti-bribery issues, the law is silent on disclosure requirements and reporting obligations towards the health authorities relating to any sponsorship, donation or grant to HCPs and healthcare institutions, or the seminars and events organised by a pharmaceutical company.

However, details of donations, sponsorships and gifts will be assessed and represented as part of the auditing process, and reported as per the request of a relevant authority, on a case-by-case basis.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

These transparency requirements do not apply to foreign companies and/or companies that do not yet have products on the market.

11. PHARMACEUTICAL ADVERTISING: ENFORCEMENT

11.1 Pharmaceutical Advertising: Enforcement Bodies

The DAV, along with inspectors under the MOH and local Departments of Health, monitors compliance with advertising regulations.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The authorities (including DAV or MOH inspectors) may initiate proceedings against entities for drug advertising infringements when the infringements are discovered. Companies may proactively alert the authorities about any infringements. It is not necessary for most pharmaceutical advertising infringements to be handled in court, unless they are related to the

advertising of counterfeit drugs or are instances of repeated false advertising.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

Violations of regulations on pharmaceutical advertising can be subject to a fine of up to VND80 million (about USD3,400). In addition, the relevant companies may be forced to suspend operations for three to six months, or the material and financial benefits from the acts may be confiscated, depending on the specific case. Furthermore, the violator will be forced to recall and remove infringing elements in some cases; and where the infringing element cannot be removed, the product will have to be destroyed.

11.4 Relationship between Regulatory Authorities and Courts

When self-regulatory authorities notice any pharmaceutical advertising infringements, they may apply internal sanctions, such as suspending the violator's membership. The self-regulatory authorities may also alert the authorities about the infringements.

There does not appear to be any other relationship between measures taken by the self-regulatory authority and the procedures before or taken by courts/authorities.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In COVID-19 situations, many entities have released false advertisements on anti-COVID-19 products. The MOH and other authorities have proactively conducted inspection activities to handle infringements relating to COVID-19 prevention and treatment.

Tilleke & Gibbins is a South-East Asian regional law firm with over 200 lawyers and consultants practising in Cambodia, Indonesia, Laos, Myanmar, Thailand and Vietnam. The firm provides full-service legal assistance to investors and companies that drive economic expansion in Asia. Established in Bangkok in 1890, today Tilleke & Gibbins is a major international firm with offices in six countries that prioritises understanding its clients' businesses and working with them towards their commercial goals. The firm is known for its deep local knowledge and commitment to this fast-developing part of the world, which is especially valuable to global companies needing to navigate unfamiliar markets and regulatory environments in South-East Asia. Clients who engage Tilleke & Gibbins are given a team of advisers who provide clear, practical advice; who are responsive in communications; who represent them with integrity; and who guide their clients through the available options to arrive at the most effective course of action, whether this means following well-established procedures or applying an innovative approach.

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